K955837



510(k) SUMMARY

Contact Person: Judy English Date Prepared: December 22, 1995

Trade Name: Cannulated PLUS™ Hip Screw (Sterile)

Common Name: Hip Bone Screw

Classification:

Predicate Device: Cannulated PLUS™ Hip Screw

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Description/Intended Use

The Cannulated PLUS™ Hip Screw (Sterile) is a cannulated bone screw. An optional beveled washer is available for use with osteoporotic bone. The device is available in a range of sizes to fit varying anatomical requirements.

The Cannulated PLUS™ Hip Screw (Sterile) is intended to be used in the fixation of cancellous bone, for treatment of conditions such as, but not limited to:

- 1. femoral neck fractures:
- 2. arthrodesis of the hip;
- 3. femoral condyle fractures;
- tibial plateau fractures;
- 5. ankle malleolar fractures; or
- 6. **elbow** fractures

Material

The Cannulated PLUS™ Hip Screw (Sterile) is manufactured from stainless steel. The optional washer is also manufactured from stainless steel.